

## II. Remarks

### A. Status of the Claims

Reconsideration and allowance of the subject application are respectfully requested. Claims 1, 2, 5-7, 9-12, 69, and 70 are currently pending. Claim 1 is independent. By this amendment, Claim 1 has been amended in a non-narrowing manner for clarity purposes, and has not been amended for any reason related to patentability, and Claim 71 has been added to define the invention in another form. Support for new Claim 71 may be found at paragraphs [0081]-[0083] and elsewhere in the as-filed application. Thus, upon entry of this amendment, Claims 1, 2, 5-7, 9-12, 69, 70 and 71 will be pending in the subject application. No new matter has been added.

### B. January 29, 2009 Examiner Interview

Applicants would like to thank Examiner Yu for the personal interview conducted on January 29, 2009. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the January 29, 2009 Interview Summary and in the following remarks.

In the interview, Applicants' representative argued that Zhang does not teach a reference electrode with any antibodies and Oberhardt does not teach non-specific binding and therefore does not produce a signal related to non-specific *binding*. Applicants' representative pointed out that the second antibody immobilized on the second immunosensor binds to an endogenous or exogenous protein to mimic the surface of the first immunosensor and therefore produces a signal that is related to non-specific binding to the first immunosensor. The Office agreed that the claims do not read on the instant rejection and further search would be required.

### C. Rejections Under 35 USC §103(a)

Claims 1, 2, 5-7, 9, 10, 12, 69 and 70 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,670,115 ("Zhang") in view of U.S.

Patent No. 4,280,815 ("Oberhardt") further in view of U.S. Patent No. 6,087,088 ("Piran"). Applicants traverse this rejection.

The invention of independent Claim 1 is an immunosensor system with reduced interference. The system comprises a first immunosensor that includes a first immobilized antibody and generates a first signal based on a sandwich between the first immobilized antibody, a target analyte and a labeled antibody, wherein a portion of the first signal arises from non-specific binding of the labeled antibody, e.g., on and/or in the region of the first immunosensor. The system also comprises a second immunosensor that includes a second immobilized antibody and acts as an immunoreference sensor and generates a second signal that is the same as or predictably related to the degree of **non-specific binding** which occurs on and/or in the region of the first immunosensor, and has an **immunocomplex between the second immobilized antibody and an endogenous or exogenous protein** that is in a sample and that is not the target analyte. An analyzer is configured to determine a corrected signal from the first and second signals.

In the outstanding Office Action, it was indicated and Applicants agree that Zhang fails to teach the claimed second immunosensor that includes a second immobilized antibody and acts as an immunoreference sensor that generates a second signal that is predictably related to the degree of non-specific binding on (and/or in the region of) the first immunosensor and also fails to specifically teach that the immunoreactive compound is an endogenous or exogenous protein. To remedy this deficiency, the Action relies on Oberhardt and Piran. Applicants submit that neither of these secondary references teaches or suggests the claimed second immunosensor, and, accordingly, the rejection of Claim 1 and the claims depending therefrom should be withdrawn.

Oberhardt, for example, is directed to a competitive immunoassay format in which unlabeled target antigens in a sample compete with a known amount of labeled antigens for binding sites on an immobilized antibody. According to Oberhardt, some

labeled antigens may come too close in proximity to the electrode surface producing a signal and resulting in background noise. ('815 patent at Col. 6, lines 14-22.) This **proximity** interference is entirely different from the non-specific **binding** interference addressed by the claimed invention. Accordingly, like Zhang, Oberhardt also fails to teach or suggest a second immunosensor that acts as an immuno-reference sensor and generates a second signal that is the same as or predictably related to the degree of **non-specific binding** which occurs on and/or in the region of the first immunosensor. Oberhardt also fails to disclose or suggest a second immunosensor that has an **immunocomplex between the second immobilized antibody and an endogenous or exogenous protein**. For at least these reasons, Oberhardt fails to remedy the deficiencies of Zhang.

Piran is directed to an assay system that corrects for the presence of interfering substances and is completely silent concerning non-specific binding. (Abstract). As a result, Piran fails to teach or suggest a second immunosensor that acts as an immuno-reference sensor and generates a second signal that is the same as or predictably related to the degree of **non-specific binding** which occurs on or in the region of the first immunosensor. Moreover, the Piran system uses two or more different labels, some of which are used to detect the analyte and the others of which are used to detect the interfering substances. (Id.) Thus, in the Piran system, it is critical that the signals emanating from the different labels are distinguishable from one another. ('088 Pat. at Col. 4, lines 44-47.) This is entirely different from the claimed invention, which uses the same label with the first and second immunosensors. For at least these reasons, Piran also fails to remedy the deficiencies of Zhang.

Claim 11 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Zhang in view of Oberhardt further in view of Piran and Pourmand (US2002/0155476). Applicants traverse this rejection. For the reasons indicated above, Claim 1 is allowable over the references of record. Since Claim 11 depends from Claim 1, Applicants submit that it also is in condition for allowance.

D. Conclusion

In view of the above amendments and remarks, it is believed that this application is now in condition for allowance, and a Notice thereof is respectfully requested.

Applicants' attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3858. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Justin L. Krieger/  
Attorney for Applicants  
Justin L. Krieger  
Registration No. 47,719

KATTEN MUCHIN ROSENMAN L.L.P.  
2900 K St., NW  
Suite 200  
Washington, D.C. 20007-2501  
Tel: (202) 625-3858  
Fax: (202) 295-1166  
Customer No.: 27160